



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2020-0564; FRL 10020-77-ORD]

Multiple-Path Particle Dosimetry (MPPD) Model Software (MPPD EPA 2021 v.1.01) with Technical Support Documentation and User's Guide (External Review Draft)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is announcing an external expert peer review and public comment for the EPA Multiple-Path Particle Dosimetry (MPPD) Model Software (MPPD EPA 2021 v. 1.01) and its associated “Technical Support Documentation and User's Guide (External Review Draft)” ([EPA/600/R-20/406]). The document was prepared by the Center for Public Health and Environmental Assessment (CPHEA) within EPA's Office of Research and Development (ORD), with contributions from Applied Research Associates, Inc., and Fred J. Miller, LLC. EPA is releasing this draft model software version and associated document to seek review by external experts and the public. This external review draft document and model software (MPPD EPA 2021 v. 1.01) are not final and do not represent, and should not be construed to represent, any final Agency policy or views. When revising the document and the model software, EPA will consider any peer or public comments submitted during the public comment period specified in this document.

DATES: The 30-day public comment period begins **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and ends **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICAITON IN THE FEDERAL REGISTER]**. Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICAITON IN THE FEDERAL REGISTER]**.

ADDRESSES: The EPA Multiple-Path Particle Dosimetry (MPPD) Model Software (MPPD EPA 2021 v. 1.01) and its associated “Technical Support Documentation and User's Guide”

(External Review Draft)” will be available from the contractor managing the external peer review, Eastern Research Group, Inc. (ERG). To obtain a copy of the external review draft or the associated MPPD software (EPA 2021 v. 1.01), contact ERG at email: peerreview@erg.com with the Subject line: MPPD EPA 2021 Peer Review; Phone: 781-674-7362.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, contact the ORD Docket at the EPA Headquarters Docket Center; phone: 202-566-1752; fax: 202-566-9744; or email: ord.docket@epa.gov. For technical information, contact Annie M. Jarabek; phone: 919-637-6016; or email: jarabek.annie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information About the Document and MPPD Model Software

The EPA is undertaking an external peer review of an EPA version of the Multiple-Path Particle Dosimetry (MPPD) model (MPPD EPA 2021 v. 1.01) and its software, together with an EPA Technical Support Documentation and User’s Guide. The EPA introduced formal dosimetry modeling into its derivation procedures for risk assessment of inhaled materials with its 1994 document entitled “Methods for Derivation of Inhalation Reference Concentrations (RfCs) and Application of Inhalation Dosimetry” (US EPA, 1994). These methods relied upon the Regional Deposited Dose Ratio (RDDR) model and underwent two expert technical panel and two expert Science Advisory Board (SAB) reviews prior to finalization. The dosimetry adjustments were also subsequently incorporated into the Agency’s guidelines for carcinogen risk assessment (US EPA, 2005).

The EPA RDDR model was an empirical model fit to a unique set of experimental data from inhalation studies across five laboratory animal species commonly used in testing for regulatory risk assessment as well as for humans. The model provided predictions of inhaled deposited dose in various regions of the respiratory tract, including the extrathoracic (ET), tracheobronchial (TB), pulmonary (PU), thoracic (TB + PU) or total respiratory tract (TOTAL).

However, since 1994, mechanistic modeling of inhalation dosimetry for particles has

matured. The MPPD model and its software include many modernized features, with some dose metric predictions now based on mechanistic descriptions instead of empirical fitting, the ability to address a wider range of particle size, providing prediction of retained mass for some species, and including some different test species.

The EPA is convening this external peer review to evaluate the MPPD model. The model results provide dosimetry adjustment of inhalation exposures for the following purposes: interspecies extrapolation, evaluation of intra-human variability, informing experimental design, and in vitro to in vivo (IVIVE) extrapolation.

The EPA Multiple-Path Particle Dosimetry (MPPD) Model Software (MPPD EPA 2021 v. 1.01) and its associated “Technical Support Documentation and User’s Guide (External Review Draft)” will be discussed at a virtual external expert peer review meeting, which will be open to the public. In addition to the opportunity to submit written comments during the public comment period announced in this notice, the public will have an opportunity to make brief oral comments during the virtual expert peer panel meeting. For more information about the peer review meeting, including information about how to register, please visit:

<https://projects.erg.com/conferences/peerreview/register-mppd.html>.

II. How to Submit Technical Comments to the Docket at www.regulations.gov

Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with appointment only, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via the web at <https://www.regulations.gov/> or via email at ord.docket@epa.gov, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit <https://www.epa.gov/dockets>.

Submit your materials identified by Docket ID No. **EPA-HQ-ORD-2020-0564** by one of

the following methods:

- www.regulations.gov: Follow the online instructions for submitting comments.
- E-mail: ord.docket@epa.gov.
- Fax: 202-566-9744.
- Mail: Office of Research and Development (ORD) Docket (Mail Code: 28221T),

U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

The phone number is 202-566-1752.

- Hand Delivery: The ORD Docket is located in EPA's Headquarters Docket Center, Room 3334 EPA West Building, 1301 Constitution Ave., NW, Washington, DC. If you provide materials by mail or hand delivery, please submit three copies of these materials. For attachments, provide an index, number pages consecutively with the materials, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. **EPA-HQ-ORD-2020-0564**.

Please ensure that your comments are submitted within the specified comment period.

Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at www.regulations.gov, including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact

information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit EPA's Docket Center homepage at www.epa.gov/epahome/dockets.htm.

Docket: Documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket in EPA's Headquarters Docket Center.

Authority: Pub. L. 94-475; Environmental Research, Development, and Demonstration Authorization Act of 1976.

Dated: February 18, 2021.

Vanessa Holt,

Acting Director,

Center for Public Health and Environmental Assessment (CPHEA).

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